

TITLE: An Analysis of Functional Status in Multiple Sclerosis Patients after Progressive Non-Aerobic High-Intensity Maximal Effort Exercise (MEE)

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ABSTRACT:

BACKGROUND: Multiple Sclerosis (MS) is a disease with a wide-ranging impact on functional status. MS patient function has been assessed using Multiple Sclerosis Functional Composite Score (MSFCS). The MSFCS includes the standardized scores (Z-score) of three functional tests: the Paced Auditory Serial Addition Test (PASAT-3") for cognitive function, 9-Hole Peg Test (9-HPT) for upper extremity function, and timed 25-foot walk (25-TW) for lower extremity function. One of the most common symptoms experienced by MS patients is severe fatigue, often brought on suddenly by aerobic exercise. Non-aerobic maximal effort exercise (MEE) is thought to increase strength without increasing fatigue. The IsoPUMP® (Neuromuscular Engineering; Nashville, TN) is a stationary exercise device designed for patient use to safely perform MEE leg presses and whole body lunges using isometric and eccentric exercises. The progressive functional changes of the MS patients were tracked using the MSFCs at specific intervals during the study.

HYPOTHESIS: An observed functional improvement in patients will be reflected in their MSFCS as well as the individual PASAT-3", 9-HPT, and 25-TW tests.

MATERIALS & METHODS: A total of 78 subjects, diagnosed with MS for at least 2 years, participated in this multi-centered study. During the baseline period, subjects completed questionnaires and performed the 25-TW, 9-HPT, and PASAT-3" test. A four-phase exercise protocol was implemented using leg press and whole body lunge exercises performed on the IsoPUMP® bi-weekly for 10 weeks and once during weeks 16 and 22. Subjects were instructed to perform a valsalva while exerting their maximal effort against the IsoPUMP® resistance for 4 seconds per repetition. This was repeated several times with minimal rest (60-180 seconds) between progressively more repetitions (3 at onset; 5 after week 7.) Effect size, calculated by comparing baseline (Week 0) mean MSFC Z-score values to values obtained from subsequent weeks, was employed to determine the statistical significance of the improved function and strength.

RESULTS: Significant improvements in the cognitive function (Effect Size =0.64, p-value< 0.001), lower extremity function (Effect Size=0.39, p-value=0.001) and overall MSFC (Effect Size = 0.32, p-value< 0.001) were noted twelve weeks post-MEE treatment. However, the changes in the upper extremity function were not statistically significant.

CONCLUSION: When comparing MS subject's functional status to baseline, it was noted that the subjects showed significant improvement in cognition (moderate) and lower extremity

function (mild), with prolonged effects lasting twelve weeks post MEE treatment. Although changes in upper extremity function were not statistically significant, an improvement in overall function, quantified as an enhanced MSFC score, was noted over the 6-month total observation time. While an effect-size of 0.32 for overall MSFC indicates a mild statistical improvement, it is considerably significant in this patient population, where the underlying disease process predisposes them to deterioration in function over time.

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